REMARKS

Claims 21-38, 40-46, 48-54, 56, 57 and 63 are currently pending in this application. No new matter has been added.

Obviousness rejections over Muller are Overcome

Claims 21-38, 40-46, 48-54, 56, 57 and 63 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Muller (U.S. Patent No. 5,858,410) in view of Andersson (U.S. Patent No. 5,739,152). Applicant disagrees.

Specifically, the Examiner indicates that Muller teaches nanosuspensions comprising lecithin and compounds selected from polyvinyl alcohol, ploxamer, glucose, mannose trehalose and sorbitol in addition to other active agents and autoclaving. (*See*, 09-21-06 Office Action at page 3). The Examiner acknowledges that Muller does not teach autoclaving a dispersion of active agent under nitrogen to achieve a stable compositions, which is taught by Andersson. (*See*, 09-21-06 Office Action at page 3).

The claims recite a water insoluble active substance and phospholipid surface modifiers in a specified ratio and a specified mean particle size that are combined with other components in addition to surfactants. Compositions that contain only phospholipid stabilizers and no other surfactant can be difficult to autoclave. (*See*, Specification at page 1, third paragraph). Although Muller discusses formulation stability after autoclaving, Muller does not teach or suggest how autoclaving phospholipid only-stabilized (*i.e.*, no surfactant) formulations will affect particle size. Specifically, Example 10 examines stabilization following autoclaving, yet in this example TWEEN 80 is present in the formulation which acts as a surfactant. (*See*, Muller at column 15, lines 28-67). As evident by the Examples in the instant application, it is more than merely adding a surfactant to compositions in order to maintain the particle size. Specifically, Examples 1 and 2 in the instant application not only show how the different surfactants themselves but also how the amount of the surfactants affect the particle size. (*See*, Specification at pages 5-9). Example 1 demonstrates the successful use of surfactants in preparations of the compositions. (*See*, Specification at page 6, Table 1). In Example 2, the earlier formulations did not have the addition of the surfactants, and therefore, the solid drug could not be dispersed in the water. (*See*, Specification at page 7). Formulations D and E, however, contained surfactants of varying

amounts and type which allowed the solid drug to be dispersed, however, as Table II shows, the particle size increased too much after sterilization with formulation. (*See*, Specification at page 7, Table 2). As such, Muller does not render obvious applicant's claims because it does not address how the use of surfactants in compositions containing phospholipids affects particle size.

The Andersson disclosure does not cure the deficiencies in Muller. Accordingly, the combination of Andersson with Muller also does not render obvious the presently amended claims. Applicants submit that the claims are now allowable.

Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted, Reg. No. 58,032

FDV

Ivor R. Elrifi, Reg. No. 39,529
Naomi S. Biswas, Reg. No. 38,384
Attorneys for Applicants
MINTZ, LEVIN
Tel: 617-542-6000
Fax: 617-542-2241
Customer No. 30623

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